

**REMARKS**

Claims 1-10 are pending in the present application. Claims 1, 2, 4, 6, and 8 have been amended. No new matter has been introduced by these amendments. Reconsideration and allowance is respectfully requested in view of the amendments and the following remarks.

Claims 1-4 have been rejected under 35 U.S.C. § 103(a), as being unpatentable over Kittrell et al. (U.S. Patent No. 5,304,173) in view of Clift (U.S. Patent No. 5,452,716). Claim 5 has been rejected under 35 U.S.C. § 103(a), as being unpatentable over Kittrell et al. (U.S. Patent No. 5,304,173) as applied to Claim 1, and further in view of Haaland et al. (U.S. Patent No. 5,596,992). Applicant respectfully disagrees with the Examiner's contentions.

Claim 1 has been amended to clarify the invention, stating the "analysis of an in vivo biological samples."

For an obviousness rejection to be proper, the Examiner must meet the burden of establishing that all elements of the invention are disclosed in the prior art; that the prior art relied upon, coupled with knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or combined references; and that the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988); *In Re Wilson*, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970); *Amgen v. Chugai Pharmaceuticals Co.*, 927 U.S.P.Q.2d, 1016, 1023 (Fed. Cir. 1996).

A factor cutting against a finding of motivation to combine or modify the prior art is when the prior art teaches away from the claimed combination. A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a

direction divergent from the path that the applicant took. See *In re Gurley*, 31 USPQ 2d 1130 (Fed. Cir. 1994).

The Examiner states that the Kittrell et al. reference does not teach the use of Fourier Transform IR spectroscopy (FTIRS). The Examiner contends that the Clift reference teaches the use of FTIRS and ATR for detecting radiation from a biological sample. (Office Action, Paper No. 9, page 3) One would not be motivated to combine the Clift reference with the Kittrell et al. reference. The Clift reference teaches:

Other methods such as are disclosed in Swiss patent CH 612,271 have described the use of A.T.R. (Attenuated Total Reflection) prisms and the use of spectroscopy by means of a Fourier Transform Infra-red Spectroscope. These methods have been made inaccurate by the inability of such a method to accurately correct for the varied concentrations of other components of blood, for example, varying hemoglobin and fat, whose spectra overlay that of glucose (see also Clinical Chemistry Vol. 35, No. 9 1854-1856). The light must enter and exit the prism at a precise angle and a fluid being examined must cover a constant surface area. These requirements as well as other variables such as temperature of the prism, make the application to a patient difficult and remote sensing, such as bed side monitoring, impossible. Also the "evanescent" wave produced by these A.T.R. systems penetrates less than 1 micron into the surrounding fluid making them impossible to use across a membrane or through skin for measuring blood sugar. (Col. 2, lines 45-62)

The Clift reference specifically teaches away from using ATR prisms and the use of spectroscopy by means of a FTIRS because the methods have been made inaccurate by the inability to accurately correct for the varied concentrations of other components of blood. The Clift reference specifically teaches away from using ATR and FTIRS, therefore one would not be motivated to combine the Clift reference with the Kittrell et al. reference. Likewise, one would not be motivated to combine the Clift reference with the Kittrell et al. reference and the Haaland et al. reference. Therefore, the claims are not *prima facie* obvious.

Additionally, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the

teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). The Kittrell et al. reference teaches a spectral diagnostic system that removes diseased tissue and further analysis is completed in a laboratory in which samples are placed in cuvettes and analyzed. (Col. 21, lines 10-64) This is an in vitro process. Thus, the Kittrell et al. reference teaches the principle of in vitro processes. In contrast, the present application claims “analysis of an in vivo biological samples.” One of ordinary skill in the art understands that in vitro processes are completely different than in vivo processes. To modify the Kittrell et al. patent as is recited in the present application’s claims would change the principle of operation of the Kittrell et al. invention. Therefore, the claims are not *prima facie* obvious.

Likewise, the proposed modification of the Kittrell et al. reference with the Clift reference and the Haaland et al. reference also fails. The Kittrell et al. reference teaches an opposite method of analysis from the Clift reference and the Haaland et al. reference. That is, in vitro vs. in vivo. Therefore, the references cannot be combined. Therefore, the claims are not *prima facie* obvious.

There is no motivation to combine these references, since the Clift teaches away from the use of ATM and FTIRS, and the Kittrell et al. reference teaches a different principal of operation than the Clift reference and the Haaland reference. Further, the Kittrel et al. reference teaches a different principal of operation than the claimed invention. Therefore, the Examiner has failed to make a *prima facie* case of obviousness.

The Examiner contends that it would have been obvious to someone of ordinary skill in the art at the time of the invention to use a FTIRS for spectral analysis, that spectral analysis could be performed with a standard Fourier spectrophotometer operating in the claimed spectral range, and to employ the practice well known in the art of using catheter systems with means for changing probes. (Office Action, Paper No. 9, page 3)

Identification of prior art statements that, in abstract, appear to suggest claimed limitations does not establish *prima facie* case of obviousness without finding as to specific understanding or principle within knowledge of skilled artisans that would have

motivated one with no knowledge of the invention at issue to make a combination in the manner claimed. *In re Kotzab*, 55 USPQ2d 1314, (Fed. Cir. 2000). The motivation, suggestion or teaching may come explicitly from statements in the prior art, the knowledge of one of ordinary skill in the art, or, in some cases the nature of the problem to be solved. *In re Kotzab*, 55 USPQ2d 1317, (Fed. Cir. 2000). The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art. *In re Keller*, 208 USPQ 871, 881 (CCPA 1981). Whether the Board relies on an express or an implicit showing, it must provide particular findings related thereto. *In re Kotzab*, 55 USPQ2d 1317, (Fed. Cir. 2000). Broad conclusory statements standing alone are not evidence. *In re Kotzab*, 55 USPQ2d 1317, (Fed. Cir. 2000).

Thus, reliance on the obviousness rejection based upon obvious ranges, obvious instruments, and obvious practices is not sufficient without evidence from the prior art. It is respectfully requested that evidence be provided, if possibly citable from the prior art references, to prove that the prior art teaches the claimed instruments, spectral ranges, and practices, or the rejection must be withdrawn.

Additionally, if an independent claim is non-obvious under 35 U.S.C. 103, then any claim depending therefrom is non-obvious. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). Claim 1 is non-obvious over the prior art, therefore, dependent Claims 2-5 are also non-obvious over the prior art.

Reconsideration and withdrawal of these rejections is respectfully requested.

Claims 6-10 have been rejected under 35 U.S.C. § 103(a), as being unpatentable over Kittrell et al. (U.S. Patent No. 5,304,173) in view of Haaland et al. (U.S. Patent No. 5,596,992) and further in view of Clift (U.S. Patent No. 5,452,716). Applicant respectfully disagrees with the Examiner's contentions.

As stated above, for an obviousness rejection to be proper, the Examiner must meet the burden of establishing that all elements of the invention are disclosed in the

prior art; that the prior art relied upon, coupled with knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or combined references; and that the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988); *In Re Wilson*, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970); *Amgen v. Chugai Pharmaceuticals Co.*, 927 U.S.P.Q.2d, 1016, 1023 (Fed. Cir. 1996).

As stated above, a factor cutting against a finding of motivation to combine or modify the prior art is when the prior art teaches away from the claimed combination. A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that the applicant took. See *In re Gurley*, 31 USPQ 2d 1130 (Fed. Cir. 1994).

The Examiner states that the Kittrell et al. reference and the Haaland et al. reference do not teach the use of FTIRS for analysis of detected radiation. The Examiner contends that the Clift reference teaches the use of FTIRS and ATR for detecting radiation from a biological sample. (Office Action, Paper No. 9, page 4) One would not be motivated to combine the Clift reference with the Kittrell et al. reference and the Haaland et al. reference. The Clift reference teaches:

Other methods such as are disclosed in Swiss patent CH 612,271 have described the use of A.T.R. (Attenuated Total Reflection) prisms and the use of spectroscopy by means of a Fourier Transform Infra-red Spectroscope. These methods have been made inaccurate by the inability of such a method to accurately correct for the varied concentrations of other components of blood, for example, varying hemoglobin and fat, whose spectra overlay that of glucose (see also Clinical Chemistry Vol. 35, No. 9 1854-1856). The light must enter and exit the prism at a precise angle and a fluid being examined must cover a constant surface area. These requirements as well as other variables such as temperature of the prism, make the application to a patient difficult and remote sensing, such as bed side monitoring, impossible. Also the "evanescent" wave produced by these

A.T.R. systems penetrates less than 1 micron into the surrounding fluid making them impossible to use across a membrane or through skin for measuring blood sugar. (Col. 2, lines 45-62)

The Clift reference specifically teaches away from using ATR prisms and the use of spectroscopy by means of a FTIRS because the methods have been made inaccurate by the inability to accurately correct for the varied concentrations of other components of blood. The Clift reference specifically teaches away from using ATR and FTIRS, therefore one would not be motivated to combine the Clift reference with the Kittrell et al. reference or the Haaland et al. reference. Therefore, the claims are not *prima facie* obvious.

Additionally, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). The Kittrell et al. reference teaches a spectral diagnostic system that removes diseased tissue and further analysis is completed in a laboratory in which samples are placed in cuvettes and analyzed. (Col. 21, lines 10-64) This is an in vitro process. Thus, the Kittrell et al. reference teaches the principle of in vitro processes. In contrast, the present application claims “analysis of an in vivo biological samples.” One of ordinary skill in the art understands that in vitro processes are completely different than in vivo processes. To modify the Kittrell et al. patent as is recited in the present application’s claims would change the principle of operation of the Kittrell et al. invention. Therefore, the claims are not *prima facie* obvious.

Likewise, the proposed modification of the Kittrell et al. reference with the Clift reference and the Haaland et al. reference also fails. The Kittrell et al. reference teaches an opposite method of analysis from the Clift reference and the Haaland et al. reference. That is, in vitro vs. in vivo. Therefore, the references cannot be combined. Therefore, the claims are not *prima facie* obvious.

There is no motivation to combine these references, since the Clift teaches away from the use of ATM and FTIRS, and the Kittrell et al. reference teaches a different principal of operation than the Clift reference and the Haaland reference. Further, the Kittrell et al. reference teaches a different principal of operation than the claimed invention. Therefore, the Examiner has failed to make a *prima facie* case of obviousness.

The Examiner contends that it would have been obvious to someone of ordinary skill in the art at the time of the invention to use a FTIRS for spectral analysis, that quantitative analysis of spectra requires analysis of peak position, height, and enclosed area, and that quantitative analysis of spectra requires comparison of spectra that includes ratios of the claimed parameters. (Office Action, Paper No. 9, page 4)

As stated above, identification of prior art statements that, in abstract, appear to suggest claimed limitations does not establish *prima facie* case of obviousness without finding as to specific understanding or principle within knowledge of skilled artisans that would have motivated one with no knowledge of the invention at issue to make a combination in the manner claimed. *In re Kotzab*, 55 USPQ2d 1314, (Fed. Cir. 2000). The motivation, suggestion or teaching may come explicitly from statements in the prior art, the knowledge of one of ordinary skill in the art, or, in some cases the nature of the problem to be solved. *In re Kotzab*, 55 USPQ2d 1317, (Fed. Cir. 2000). The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art. *In re Keller*, 208 USPQ 871, 881 (CCPA 1981). Whether the Board relies on an express or an implicit showing, it must provide particular findings related thereto. *In re Kotzab*, 55 USPQ2d 1317, (Fed. Cir. 2000). Broad conclusory statements standing alone are not evidence. *In re Kotzab*, 55 USPQ2d 1317, (Fed. Cir. 2000).

Thus, reliance on the obviousness rejection based upon obvious instruments and obvious analysis techniques is not sufficient without evidence from the prior art. It is respectfully requested that evidence be provided, if possibly citable from the prior art

references, to prove that the prior art teaches the claimed instruments and analysis techniques, or the rejection must be withdrawn.

Additionally, if an independent claim is non-obvious under 35 U.S.C. 103, then any claim depending therefrom is non-obvious. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). Claim 6 is non-obvious over the prior art, therefore, dependent Claims 7-10 are also non-obvious over the prior art.

Reconsideration and withdrawal of these rejections is respectfully requested.

Request for Allowance

Entry of this Amendment will place the Application in better condition for allowance, or at the least, narrow any issues for an appeal. Accordingly, entry of this Amendment is appropriate and is respectfully requested.

If, in the opinion of the Examiner, an interview would expedite the prosecution of this application, the Examiner is invited to call the undersigned attorney at the number indicated below.

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Respectfully submitted,  
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